K010622

MAR 2 9 2001

SunTech Medical Instruments Inc.
Special 510(k) Submission
Pressure Trak Automatic Blood Pressure Measurement System
510(k) Summary
5 January 2001

(1) Submitter information

Name: SunTech Medical Instruments Inc.

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Raleigh, North Carolina 27617

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Contact person: David Gallick (Official Correspondent).

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Tel: 919-782-3005 x232
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Date prepared: 23 February 2001

(2) Name of Device

Trade Name: Pressure Trak - Ambulatory Blood Pressure Measurement System
Common Name: Automated Blood Pressure Monitor
Classification name: System, measurement, blood pressure, non-invasive, 74DXN, 870.1130

(3) Legally-marketed predicate devices

OSCAR 2, K003004, also made by SunTech Medical Instruments.

The Pressure Trak is substantially equivalent to this device.

(4) Description

The Pressure Trak, a microprocessor based ambulatory blood pressure monitor, uses an oscillometric step deflate technique to determine blood pressure. An internal electric pump is used to inflate the cuff, and the deflation is controlled by two valves. During cuff deflation, small cuff pressure changes (resulting from arterial blood pressure pulses) are analyzed by the microprocessor, in order to determine the blood pressure. Pressure Trak has the ability to make blood pressure measurements at predetermined intervals (normally from a schedule determined by the physician), or on demand (by using the stop/start key). Each reading is stored in memory, allowing the physician to download all the results obtained during the study period after the study has concluded, to be analyzed by the PC software. The readings can be displayed on the LCD or the LCD display can be disabled to prevent the patient from seeing the readings.

The associated AccuWin Pro PC-based program provides the setup, display and record-keeping functions of the system. A measurement schedule can be constructed with the AccuWin Pro program, and then up-loaded into the Pressure Trak monitor. Once the schedule is loaded in the PRESSURE TRAK unit the PRESSURE TRAK system is put on the patient at the physician's office or clinic. The patient then wears the monitor for the duration of the study (usually 24 hours.) After the ambulatory blood pressure (ABP) study has been completed, the stored readings in the Pressure Trak are downloaded to a PC using the AccuWin Pro program. The AccuWin Pro program provides the data in tabular and graphic form, as well as a patient report.

(5) Intended Use

The Pressure Trak system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.

(6) Testing and Validations

(a) Non-clinical Tests

The Pressure Trak has passed the following tests and validations:

- AAMI SP10 Electronic or Automated sphygmomanometers.
- EN60601-1 Medical Electrical Equipment - General requirements for Safety
- EN60601-2-30 Medical Electrical Equipment – Specific requirements for Blood Pressure monitors
- IEC 601-1-2 Electromagnetic Compatibility
- EN1060-1 Non-invasive sphygmomanometers – General Requirements
- EN1060-3 Non-invasive sphygmomanometers- Supplementary requirements for electro-mechanical blood pressure measuring systems

(b) Clinical tests

Since the Pressure Trak uses the same technology as existing devices, clinical tests are not required. However, to satisfy SunTech Medical Instrument's internal requirement of meeting AAMI SP10, the system was compared to manual readings on patients according to section 4.4.2 of AAMI SP10, and it has satisfactorily passed this test.

(7) Conclusion

The Pressure Trak Automated Blood Pressure Monitor system is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2001

Mr. David Gallick
SunTech Medical Instruments
8917 Glenwood Avenue
Raleigh, NC 27617

Re: K010622
Trade Name: Pressure Trak System, Model 222-B
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: February 23, 2001
Received: March 2, 2001

Dear Mr. Gallick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

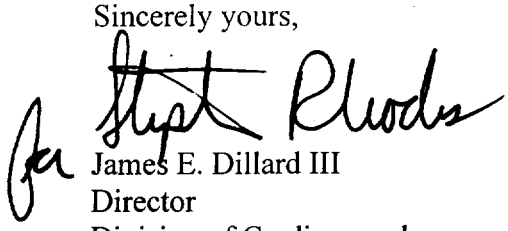
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SunTech Medical

510(k) Number (if known): K010622

Indications for Use Form

Device Name: Pressure Trak Ambulatory Blood Pressure Measurement System

Indications for Use:

The Pressure Trak is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program. The Trak is capable of recording and displaying up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010622

Prescription Use ✓ **OR** **Over-the-Counter Use**
(Per 21 CFR 810.109)

(Optional Format 1-2-96)